

## **REMARKS**

### **The Notice of Non-Compliant Amendment**

This correspondence is in response to a Notice of Non-Compliant Amendment. The Notice was sent because the Amendment filed on February 21, 2008 was a duplicate of the Amendment filed on August 7, 2007. Applicants' representative acknowledges the error noted by the Examiner and apologizes for any inconvenience caused by this error. It is believed that the error occurred when the wrong electronic document was selected for submission via the electronic filing system. Please consider the present Amendment in lieu of the Amendment submitted on February 21, 2008.

### **Status of the Claims**

Claims 38-43 are pending in the present application. Claim 38 has been amended as described elsewhere herein. Support for the amendments to claim 38 may be found in the original specification and claims as filed, including, for example, on lines 18-27 of page 76 of the specification. No new matter has been added by way of amendment.

### **The Rejection Under 35 U.S.C. § 112, Second Paragraph, Should be Withdrawn**

Claims 38 and dependent claims 39-43 have been rejected under 35 U.S.C. § 112, second paragraph, on the grounds that the phrase "identifying in an assay for GR-mediated activity a modeled ligand" makes it unclear whether the assay occurs *in vivo* or *in silico*. Claim 38 has been amended to clarify that the assay is not performed *in silico*. Support for the amendment can be found in the specification and claims as filed, including, for example, on lines 18-27 of page 76 of the specification. One of skill in the art would recognize the scope of the claims 38-43 as amended. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

### **The Rejection under 35 U.S.C. § 103 Should be Withdrawn**

The rejection of claims 38-43 under 35 U.S.C. § 103(a) has been maintained on the grounds that claims 38-43 are obvious in view of Apolito *et al.* (WO 03/015692); claims 38-42 are obvious in view of Gillner *et al.* (WO 00/52050); and claim 43 is obvious in view of

Gillner *et al.* and Hogger *et al.* (1994) *Steroids* 59(10):597-602. The rejection is respectfully traversed for the reasons described below.

The rejection hinges on the construction of the scope of claims 38-43. The Examiner argues that the atomic coordinates recited in claims 38-43 constitute non-functional descriptive matter, and that these atomic coordinates should therefore not be considered in construing the scope of the claims. The Examiner argues that when the limitation of the recited atomic are not considered, claims 38-43 are obvious in view of the cited references. According to the Office Action, the structural coordinates of Table 2 are non-functional because they do not have a functional relationship with the computer on which they are stored. The Examiner states that, "[d]ata, which are fed into a known algorithm whose purpose is to compare or modify those data uses a series of processing steps, do not impose a change in the processing steps and are thus nonfunctional descriptive material." (November 21, 2007 Office Action, page 5.) Thus, according to the Office Action, there is a *per se* rule that data stored in a computer is considered to be non-functional if the data does not affect how the computer performs its function. (November 21, 2007 Office Action, page 10).

However, the relevant case law does not support a finding that the atomic coordinates recited in claims 38-43 are non-functional descriptive matter. In *In re Gulack*, 703 F.2d 1381 (Fed. Cir. 1983), the Federal Circuit stated:

A functional relationship of the precise type found by the CCPA in *Miller*—to size or to type of substrate, or conveying information about substrate—is not required. What is required is the existence of *differences* between the appealed claims and the prior art sufficient to establish patentability....the critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.

*Id.* at 1386. In the present case, claims 38-43 are directed to methods of using of using structural information about a novel GR expanded binding pocket in the design of GR modulators that fit spatially into this novel pocket, and then testing these modeled ligands in an assay to determine if they modulate the activity of a GR polypeptide. The atomic coordinates recited in the claim 38 are integral to the step of modeling a ligand that fits

spatially into the expanded binding pocket. If a different set of atomic coordinates were used in the claimed method, the result of the method would differ from the result achieved in the method recited in claim 38. Thus the atomic coordinates recited in claim 38-43 functionally affect the process of modeling a ligand to fit within the expanded binding pocket. Accordingly, the atomic coordinates are functionally related to the claimed method and this limitation should be considered when construing the scope of these claims. The Examiner has not produced any evidence that the expanded binding pocket described by the recited atomic coordinates would be obvious in view of the prior art references. Accordingly, claims 38-43 recite differences over the prior art that are sufficient to establish patentability, thereby meeting the standard for non-obviousness set forth in *Gulack*.

Furthermore, the atomic coordinates recited in claims 38-43 of the present case are readily distinguishable over the type of descriptive matter at issue in *In re Ngai*, 367 F.3d 1136 (Fed Cir. 2004). In *Ngai*, the issue before the Federal Circuit was whether an inventor could patent a kit composition, where the only difference between the prior art and the claimed kit was the content of instructions included in the kit. The court found that the instructions did not depend on the kit, and the kit did not depend on the instructions; therefore, the addition of the instructions did not make the kit patentable. Thus in *Ngai*, the descriptive material at issue in the rejected claims was only different from the prior art in that it taught "a new use for an existing product." *Id.* At 1339. In contrast, the claims 38-43 of the present application are directed to methods of use for a new product, i.e. a novel and non-obvious GR polypeptide expanded binding pocket structure, which can be used, for example, to model ligands that fit spatially into this pocket.

In *In re Lowry*, 32 F.3d 1579 (Fed. Cir. 1994), the Federal Circuit considered whether a claim limitation reciting attribute data objects (ADOs) stored in memory should be given patentable weight in construing the claim. The court held that the data objects claimed by Lowry were functional because they increased the efficiency of data access and therefore produced a tangible benefit. *Id.* At 1584. However, the court in *Lowry* did not hold that *only* those data structures that increased computer efficiency could be considered to produce a tangible benefit. Rather, the increased efficiency of Lowry's data structures was found to be one way in which such tangible benefit could be demonstrated. Similarly, the methods

recited in claims 38-43 produce a tangible benefit because they allow for the identification of ligands that bind the GR polypeptide expanded binding pocket. Thus, these atomic coordinates are functional related to the claimed method and should be given patentable weight.

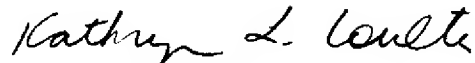
In summary, Apolito *et al.*, Gillner *et al.*, and Hogger *et al.*, either alone or in combination, do not teach or suggest all the limitations of claims 38-43 when all the limitations of these claims are properly considered. Therefore, all grounds for rejection under 35 U.S.C. § 103 have been overcome. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

**CONCLUSION**

It is believed that the current application is now in condition for allowance. Early notice to this effect is solicited. If, in the opinion of the Examiner, an interview would expedite prosecution, the Examiner is invited to call the undersigned.

Applicants believe that no fees are due in connection with the filing of this paper other than those specifically authorized herein. However, should any other fees be deemed necessary to effect the timely filing of this paper, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 07-1392.

Respectfully submitted,



Kathryn L. Coulter  
Patent Attorney  
Registration No. 45,889

Date: 5/8/2008  
Customer No. 23347  
GlaxoSmithKline  
Five Moore Drive, P.O. Box 13398  
Research Triangle Park, NC 27709-3398  
Telephone: (919) 483-1467  
Facsimile: (919) 483-7988